K092081

510(k) Summary

JUL 21 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: May. 10, 2009

1. Company and Correspondent making the submission:

Name – Vieworks Co., Ltd.

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Contact – Mr. BongGu, Lee

Internet – http://www.vieworks.com

2. Device :

Trade/proprietary name	: QXLink
Common Name	: Picture archiving and communication system(PACS)
Classification Name	: Imaging Processing System, Radiological

3. Predicate Device :

Manufacturer	: Mediface Co., Ltd.
Device	: MEDIFACE PACS
510(k) Number	: K010259(Decision Date - Jan. 29. 2001)
Manufacturer	: EMSOMA Co., Ltd.
Device	: PetaVision
510(k) Number	: K083555(Decision Date - Dec. 16. 2008)

4. Classifications Names & Citations :

21CFR 892.2050, LLZ, Imaging Processing System, Radiological, Class2

5. Description :

5.1 General

QXLink is PACS (Picture Archiving and Communication System) software for radiologist and physician doctor. QXLink enables images such as x-ray to be stored electronically and viewed on screens. QXLink conforms to the DICOM standards to allow the sharing of medical information with other digital imaging system.

Also, QXLink is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. The software components provide functions for performing operations related to image manipulation, enhancement or quantification. And images may be acquired from imaging devices such as CR, CT, MR and other devices.

QXLink consists of QXLink Server and QXLink Viewer and the main functions of QXLink are as follows.

5.2 Main Function

5.2.1 Image Archive

QXLink Server stores DICOM images that are transmitted in the form of DICOM protocol from each of various modalities. And it saves the information of that image into Database.

5.2.2 Query/Retrieve

QXLink Viewer can search the information of specific DICOM image through DICOM protocol. It queries that information using the several matching attributes (patient name, patient id, sex, study description, study id, accession number, and study date range). It requests QXLink Server to transfer the specific DICOM image.

5.2.3 Image display

QXLink Viewer displays DICOM image on the monitor as if film is read at the film view box. It has several functions to help view images, which are zoom, pan, window/level, invert and so on. It can support that a doctor reports and documents the diagnostic conclusion to the Structured Report file (DICOM format). It can also export DICOM images to CD/DVD disk

and print them to DICOM/Paper printer.

6. Indication for use :

The QXLink is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification. And Images may be acquired from imaging devices such as CR, CT, MR and other devices. This device is not intended for mammographic operations.

7. Comparison with predicate device :

Vieworks Co., Ltd., believes that the Picture archiving and communication system(QXLink) is substantially equivalent to the MEDIFACE PACS of Mediface Co., Ltd. and the PetaVision of EMSOMA Co., Ltd..

8. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Vieworks Co., Ltd. concludes that The QXLink is safe and effective and substantially equivalent to predicate devices as described herein.

9. Vieworks Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2009

Vieworks, Co., Ltd.
% Mr. Marc M. Mouser
CAS Manager II / Office Coordinator
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

Re: K092081
Trade/Device Name: Picture archiving and communication system (PACS)/QXLink
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 8, 2009
Received: July 9, 2009

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092081

Device Name: Picture archiving and communication system (PACS)/ QXLink

Indications for Use:

The QXLink is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. The software components provide functions for performing operations related to image manipulation, enhancement, compression or quantification. And Images may be acquired from imaging devices such as CR, CT, MR and other devices. This device is not intended for mammographic operations.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092081